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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/705,740

11/11/2003

Richard B. Greenwald

213.1207

4315

20311 7590 09/05/2007  
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EXAMINER
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HEARD, THOMAS SWEENEY

ART UNIT	PAPER NUMBER
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1654

MAIL DATE	DELIVERY MODE
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09/05/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/705,740	GREENWALD ET AL.	
	Examiner	Art Unit	
	Thomas S. Heard	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-33 is/are pending in the application.
- 4a) Of the above claim(s) 27-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-3, 6, and 33 is/are allowed.
- 6) ☐ Claim(s) 4-6, 9-26 is/are rejected.
- 7) ☐ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/29/2007 has been entered.

The Applicants Amendments to the claims received on 6/29/2007 is acknowledged. The text of those sections of Title 35 U.S. Code not included in the action can be found in the prior office action. Rejections or objections not addressed in this office action with respect to the previous office action mailed 3/29/2007 are hereby withdrawn.

Claim(s) 1-6, 8-33 are pending. Applicants have amended claim(s) 1, 21, 24. Applicants have cancelled claim 7. Claims 2-5, 8, 11, 12-20, 25-33 were withdrawn. However, upon further consideration, the Examiner has rejoined all product claims. The method Claims of 27-32 remain withdrawn. Claims 1-6, 8-26, and 33 are hereby examined on the merits.

Applicant's elected species has been found free of the prior art.

### **Objection**

Claim 8 is dependent on a cancelled claim. Correction if dependency is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 5, 9-20 and 26 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "(i)-R1-(i)." There is insufficient antecedent basis for this limitation in the claim because Claim 1 is drawn to a single vancomycin composition linked by a linear polyethylene glycol moiety.

Claim 5 recites the limitation ""(ii)-R1-(ii)." There is insufficient antecedent basis for this limitation in the claim because Claim 2, and its dependency on Claim 1, is drawn to a single vancomycin composition linked by a linear polyethylene glycol moiety.

Claim 9 recites the limitation "terminally branched or multi-armed polyalkylene oxide." There is insufficient antecedent basis for this limitation in the claim because a linear polyethylene glycol is claimed in Claim 1. Because Claim 10-20 depend from indefinite claim 9 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

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Claim 21 recites structures that a made from branched polyethylene glycol moieties. There is insufficient antecedent basis for this limitation in the claim because a linear polyethylene glycol is claimed in Claim 1 and Claim 21 is drawn to branched structure not envisioned in Claim 1. Because Claim 22 and 23 depend from indefinite claim 21 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claim 26 recites structures that a made from branched polyethylene glycol moieties. There is insufficient antecedent basis for this limitation in the claim because a linear polyethylene glycol is claimed in Claim 1 and Claim 26 is drawn to branched structure not envisioned in Claim 1.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 15, 24, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by 2002/0103259.

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The applied reference has a common assignee and inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

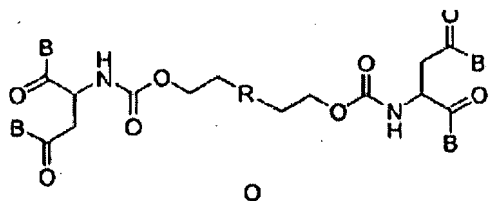
Claims 15, 24, and 25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of

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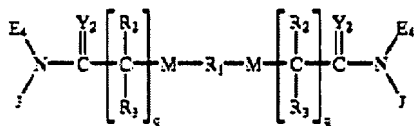
U.S. 2002/0103259 (10/067,930). Although the conflicting claims are not identical, they are not patentably distinct from each other because the vancomycin compound and the branched linkers that connect the vancomycin molecules are claimed.

Claims 15, 24, and 25 are directed to an invention not patentably distinct from claims 1-19 of commonly assigned application as vancomycin compound and the branched linkers that connect the vancomycin molecules are claimed.

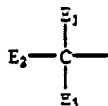
For example the species of the instant Claim 15



Can be made from



R is a polymer (polyethylene glycol), M = O, q = 0, Y2 = O, E4

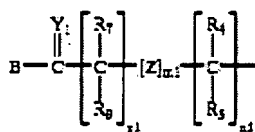


J is H

E1 is H

E2 and E3 are

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where E2; B = Vancomycin, Y1 = O, p1, N1, and m1 are 0 and

where E3 B = Vancomycin, Y1 = O, p1 = 2, N1, and m1 are 0.

### ***Allowable Subject Matter***

The following is a statement of reasons for the indication of allowable subject matter: Claims 1-3, 6, and 33 are drawn to linear polymer conjugates of polyethylene glycol and vancomycin. The closest prior art is that of US 6,180,095. While the prior art teaches linkers aromatic linkers, for example, between the PEG and Vancomycin, the prior art does not teach or suggest or provide motivation to make the specific species if linker embraced by the instant application and conjugate them to vancomycin at the specific positions claimed.

### **Conclusion**

Claims 1-3, 6, and 33 are found free of the prior art. No other claims are allowed.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted



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that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

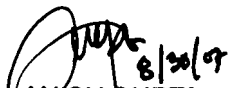
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas S. Heard whose telephone number is (571) 272-2064. The examiner can normally be reached on 9:00 a.m. to 6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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8/20/07  
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